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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,235	01/02/2004	Dean DellaPenna	MSU-08604	3881

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EXAMINER

WORLEY, CATHY KINGDON

ART UNIT	PAPER NUMBER
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1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/18/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/751,235

Applicant(s)

DELLAPENNA ET AL.

Examiner

Cathy K. Worley

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-17 and 21-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-17 and 21-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/10/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S.Code not included in this action can be found in a prior Office action.

Objections and Rejections that are Withdrawn

2. The objection to the abstract is withdrawn in light of the Applicant's amendment of the abstract.
3. The rejections of claims 5-8, 13, and 16-17 under 35 USC 112, second paragraph for being indefinite are withdrawn in light of the Applicant's amendments to the claims.
4. The rejection of claims 1-8, 11-17, 21-22, and 24-28 under 35 USC 102(e) over Kovalic et al. is withdrawn in light of the Applicant's amendments to the claims.
5. The rejection of claims 16-17 under 35 USC 102(b) over Comai et al. is withdrawn in light of the Applicant's amendments to the claims.

6. The rejection of claims 1-8 and 10-12 under 35 USC 102(b) over Nyakatura et al. is withdrawn in light of the Applicant's amendments to the claims.

7. The rejection of claims 5, 7, 11-13, 21-22, 24-26, and 28 under 35 USC 102(b) over Siminszky et al. is withdrawn in light of the Applicant's amendments to the claims.

8. The rejection of claims 1, 11-12, 21-22, 24-26, and 28 under 35 USC 102(b) over Bloksberg et al. is withdrawn in light of the Applicant's amendments to the claims.

9. The rejection of claims 1-8, 10-13, 15-17, 21-22, and 24-32 under 35 USC 103(a) over Siminszky et al. in view of Nyakatura et al. and further in view of Ohkawa et al. is withdrawn because the Applicant has argued persuasively that there is not a reasonable expectation of success for expressing SEQ ID NO:5 in a plant (see first paragraph on last page of remarks submitted on Sept. 25, 2006). It is noted that this argument supports the Examiner's position for lack of enablement.

Specification

10. The Specification remains objected to for including embedded hyperlinks.

The Applicant removed "http://" from each hyperlink, however, the remaining "www." continues to be effective as a browser-executable code. The Applicant is advised that they can replace "www." with - - on the world wide web at - - .

11. The title remains objected to for not being descriptive of the elected invention.

12. The amendment to the paragraph 0168 of the specification that is included in the papers received on Sept. 25, 2006 is objected to because this paragraph was already amended on Nov. 10, 2004, and the instant amendment does not include the changes that were made on Nov. 10, 2004. The Applicant is advised that the new amendment must be made relative to the most current version of the specification and therefore it must include the amendments that were already made. Similarly, paragraph 0328 was already amended on Nov. 10, 2004, to include SEQ ID NO:28 and SEQ ID NO:29, therefore, these should not be underlined in the most recent amendment received on Sept. 15, 2006.

Claim Rejections - 35 USC § 112

13. Claims 1-8, 11-17, and 21-32 remain rejected under 35 U.S.C. 112, first paragraph for lack of written description, for the reasons of record stated in the Office Action mailed on Mar. 21, 2006. The Applicant's arguments were fully considered and were found to not be persuasive.

The Applicant argues that in Falkner v. Inglis the Federal Circuit held that there is not a requirement for the specification to always recite the gene or sequence regardless of whether it is known in the prior art. The Applicant argues that the amino acid sequence of SEQ ID NO:4 (and SEQ ID NO:5 which encodes SEQ ID NO:4) is structural information plainly understood by a person of ordinary skill in the art. The Examiner agrees, and this is why claim 10 is sufficiently described. Polypeptides with as little as 80% identity to SEQ ID NO:4 are not taught in the prior art, therefore, the instant specification has not provided adequate written description for this large genus of molecules.

The Applicant argues that they have identified and described structural features for LUT1. This is not persuasive, however, because there is no disclosed relationship between the conserved motifs disclosed and the function of being able to complement the *lut1* mutation, which is the only disclosed function.

The Applicant further argues that the Federal Circuit court held that when the prior art includes the nucleotide information, that the information does not need

to be determined afresh and that it would serve no goal to force the patentees to recite known DNA structures. This is not persuasive, however, because the instant claims encompass a large genus of molecules wherein only one is known in the art.

The currently amended claims encompass the genus of molecules having 80% identity to SEQ ID NO:4. Because SEQ ID NO:4 is 539 amino acids in length, this recitation encompasses proteins with 107 substitutions relative to SEQ ID NO:4. This is an even larger genus of molecules than the genus encompassed the previous claims. For the reasons or record stated on pages 6-7 of the previous Office Action mailed on Mar. 21, 2006, there is not an adequate written description of the large genus being claimed.

For these reasons, the Applicants arguments are not found to be persuasive and the rejections under 35 USC 112 for lack of written description are maintained.

14. Claims 1-8, 10-15, and 21-32 remain rejected and amended claims 16-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for the reasons of record stated in the Office Action mailed on Mar. 21, 2006. The Applicant's arguments were fully considered and were found to not be persuasive.

The Applicant argues that they have taught a prokaryotic vector and a yeast expression vector, and the Applicant argues that the failed attempt taught by Tian

et al. does not provide evidence that use of other methods known in the art would be unsuccessful.

This is not persuasive, however, because there is nothing in the prior art to show successful expression of LUT1 in yeast or in a prokaryote. The prior art teaches that an attempt at expressing LUT1 in yeast was unsuccessful (see Tian et al., page 405, left column). The prior also teaches that expression of eukaryotic membrane proteins in prokaryotic systems is difficult and unpredictable (see Hannig et al., second-to-last page, right column).

The Applicant argues that in Falkner, the Federal Circuit held the law is applied to each invention in view of the state of relevant knowledge. The Applicant argues that the Examiner has relied on outdated papers published in 1993 and 1998.

This is not persuasive, however, because, between 1993/1998 and the time of filing (2004), there was no leap forward in methods of expressing LUT1 in yeast or methods of expressing membrane proteins in prokaryotes taught in the art. The instant specification has not taught any specific strategies to overcome the difficulties of attempting to express a membrane protein in a prokaryote. Furthermore, there is no evidence that the prophetic method for expressing LUT1 in yeast that is taught in the instant application is different in any way from the method attempted by Tian et al. which was not successful.

The Applicant further argues that expression of SEQ ID NO:5 produced a specific phenotype that was detected using an assay for zeinoxanthin.

This is not persuasive, however, because this phenotype was the result of complementation of the *lut1* mutation. Therefore, the *lut1* mutant plant had all the necessary components of the pathway with the exception of functional LUT1 protein. This data demonstrates that LUT1 is involved in the carotenoid biosynthetic pathway and that it is required to make zeinoxanthin. However, this does not provide evidence that LUT1 performs the rate limiting step in the reaction or is the stoichiometrically limiting component of the pathway. As was discussed in the previous Office Action, further experimentation would be required to determine if expression of LUT1 in a wild-type plant would have any effect at all on carotenoid biosynthesis (see paragraph bridging pages 9-10 in the previous Office Action).

Furthermore, Applicant's arguments to overcome the 103 rejection, especially where Applicant states that one would not have a reasonable expectation of success in producing plants expressing SEQ ID NO:5 (see first paragraph on last page of the Remarks), supports Examiner's position regarding the enablement rejection. The Examiner agrees that one would not know what phenotype would result from expressing SEQ ID NO: 5 in a wild-type plant, and there is not a reasonable expectation of success in attempts to modify carotenoid biosynthesis. In the absence of any working examples, and given the unpredictability in the art as discussed in the previous Office Action, these claims lack enablement.

The Applicant is invited to submit evidence in the form of data/declaration under 37 CFR 1.132 showing that a nucleic acid encoding SEQ ID NO:4 can be successfully expressed in yeast or E. Coli, or evidence in the form of data/declaration under 37 CFR 1.132 showing that SEQ ID NO:5 or a nucleic acid encoding SEQ ID NO:4 can be expressed in a wild-type plant and that this expression resulted in a change in carotenoid biosynthesis relative to the non-transformed wild-type plant. The Applicant is reminded that even if such evidence is provided, the enablement would be limited in scope to expression of nucleic acids encoding SEQ ID NO:4, and would be limited in scope to the type of host used for the expression.

For these reasons, the Applicants arguments are not found to be persuasive and the rejections under 35 USC 112 for lack of enablement are maintained.

15. All claims remain rejected.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is

filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner has a variable schedule but can normally be reached on M-F 10:00 - 4:00 with variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CKW
Dec. 4, 2006

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PRIMARY EXAMINER
Medina A. Ibrahim